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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/606,763	06/29/2000	Hui Chen	1440.1043-001	7609

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EXAMINER
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KAM, CHIH MIN

ART UNIT	PAPER NUMBER
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1653

DATE MAILED: 11/20/2001

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Applicati n N .

09/606,763

Applicant(s)

CHEN ET AL.

Examiner

Chih-Min Kam

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 15 October 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-7, 12, 13, 17, 19 and 37-42 is/are pending in the application.
- 4a) Of the above claim(s) 8-11, 14-16, 18, 20-26 and 43-89 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-7, 12, 13, 17, 19 and 37-42 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5. 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicant's election of Group I, claims 1-7, 12-13, 17, 19 and 37-42 in Paper No. 9 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-7, 12-13, 17, 19 and 37-42 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-7, 12-13, 17, 19 and 37-42 are indefinite because of the use of the term "hCOMP" or "COMP". The term "hCOMP" or "COMP" renders the claim indefinite, it is unclear what the term means. A full spelled word should precede the term at the first occurrence.

3. Claims 1-7 are indefinite because they lack essential steps as claimed in the method of preparing purified hCOMP. The omitted steps are: introducing DNA encoding hCOMP into a vector, transforming or transfecting the clone into the cell and the method of purifying hCOMP. Claims 2-7 are included in the rejection because they are dependent on a rejected claim and do not correct the deficiency of the claim from which they depend.

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4. Claims 1-7 are indefinite because of the use of the term “introducing DNA encoding hCOMP into cells”. The term “introducing DNA encoding hCOMP into cells” renders the claim indefinite, it is unclear which cells are used for transformation. Claims 2-7 are included in the rejection because they are dependent on a rejected claim and do not correct the deficiency of the claim from which they depend.

5. Claims 5, 6 and 37-42 are indefinite because of the use of the term “at least”. The term “at least” renders the claim indefinite, it is unclear what is the maximal calcium concentration, or how many biological matrices are in the composition. Claims 38-42 are included in the rejection because they are dependent on a rejected claim and do not correct the deficiency of the claim from which they depend.

6. Claims 12 and 13 are indefinite because of the use of the term “bands of 50 kDa or 55 kDa” or “bands of 62 kDa or 67 kDa”. The term “bands of 50 kDa or 55 kDa” or “bands of 62 kDa or 67 kDa” renders the claim indefinite, it is unclear how the cleavage products of hCOMP would be different as hCOMP was digested by trypsin.

7. Claim 39 is indefinite because of the use of the term “a differentiation agent”. The term “a differentiation agent” renders the claim indefinite, it is unclear what compound is used as a differentiation agent.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 1, 2, 4, 5 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hecht *et al.* (Matrix Biology 17, 269-278 (1998)) taken with Lawler *et al.* (J. Biol. Chem. 258, 12098-12101 (1983)).

Hecht *et al.* teach a full length human COMP is expressed in baculovirus system using pFASTBAC1 plasmid and SF9 cells are used to generate the viruses. Pass 2 viruses in SF900II serum-free medium are used to produce recombinant proteins (page 271, right column-page 272 left column). However, Hecht *et al.* do not indicate the purification of the protein. Lawler *et al.* indicate a thrombospondin, a cartilage oligomeric matrix protein is purified by a heparin-Sepharose 4B column and the elution is carried out in the presence of 2 mM CaCl<sub>2</sub> (page 12098, right column, paragraph 4). At the time of invention was made, it would have been obvious to one of ordinary skill in the art to purify the protein taught by Hecht *et al.* with the method by Lawler *et al.* to obtain a more purified material for studying the properties of the protein. Thus, the combined references result in the claimed invention and was, as a whole, *prima facie* obvious at the time the claimed invention was made.

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9. Claim 37 is rejected under 35 U.S.C. 103(a) as being unpatentable over Heinegard *et al.* (WO 98/46253) taken with Junginger *et al.* (U. S. Patent 4,666,702).

Heinegard *et al.* teach a pharmaceutical composition comprising COMP, fragments or analogs for prevention or treatment of arthritic conditions. The pharmaceutical composition comprising COMP can be tablets which may be coated with a suitable polymer (page 13, line 25- page 14, line 9). However, Heinegard *et al.* do not reveal the identity of the polymer. Junginger *et al.* teach a drug delivery system for controlled release of active material comprising a core and a coating layer enclosing the core and the coating material contains a porous synthetic thermoplastic polymer such as polylactic acid (column 4, lines 1-10; Example 2). At the time of invention was made, it would have been obvious to one of ordinary skill in the art to prepare the pharmaceutical composition containing the active ingredient taught by Heinegard *et al.* in tablet form coated with the polymer taught by Junginger *et al.* to have a better drug delivery system for treating arthritic conditions. Thus, the combined references result in the claimed invention and was, as a whole, prima facie obvious at the time the claimed invention was made.

### ***Conclusion***

10. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (703) 308-9437. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, Ph. D. can be reached on (703) 308-2923. The fax phone numbers

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for the organization where this application or proceeding is assigned are (703) 308-0294 for regular communications and (703) 308-4227 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Chih-Min Kam, Ph. D. *CMK*  
Patent Examiner

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November 15, 2001

*Christopher S. F. Low*

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